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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/549,385	Confirmation No.: 6082
Applicant	:	Thorsten Siess, et al.	
Filed	:	June 30, 2006	
Art Unit	:	3763	
Title:	:	INTRODUCTION DEVICE FOR INTRODUCING AN OBJECT INTO A VESSEL OF A BODY	
Examiner	:	Quynh-Nhu Hoang Vu	
Docket No.:	:	IMPEL.71975	
Customer No.	:	24201	December 31, 2008

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RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

This is in response to the Notice of Non-Compliant Appeal Brief mailed December 4, 2008, the response to which is due by January 4, 2009. The brief has been amended to fully comply with 37 C.F.R. 41.37(c).

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed on August 14, 2008 and the Notice of Panel Decision from Pre-Appeal Brief of September 12, 2008. A request for a one month extension of time to November 12, 2008 along with the requisite fee is being filed herewith.

INTRODUCTION

The present invention relates to an introducer for facilitating the insertion of an intravascular device into a blood vessel. The device serves to dilate intervening tissue in order to gain full access into the interior of a vessel and then provides a passageway through which the

intravascular device can be introduced. The challenge has been to limit the diameter to which the tissue is dilated in order to minimize trauma to the tissue without compromising the ability to extend an intravascular device there through.

I. REAL PARTY IN INTEREST

The real party in interest is Impella CardioSystems AG. This application was originally assigned by the inventors, Thorsten Siess and Josef Penners to Impella CardioSystems GmbH, by Assignment executed September 23, 2005 and September 26, 2005, respectively. Impella CardioSystems GmbH was subsequently restructured as Impella CardioSystems AG.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The patent application has 8 pending claims. All pending claims (1-8) were finally rejected in the final Office Action of May 14, 2008. The rejection of all claims (1-8) is being appealed.

IV. STATUS OF AMENDMENTS

A response to the final Office Action of May 14, 2008 was filed on July 11, 2008. The response did not include an amendment of any of the claims. In the Advisory Action of July 23, 2008, the Examiner indicated that the applicants' argument was unpersuasive.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to an introducer that has a configuration that marks a substantial departure from previously used introducers and, indeed, the introducers that are described in the cited references. The claimed introducer (FIG. 1, #10) includes a dilator (FIG. 1, #11) in combination with a tubular channel (FIG. 1, #15). The dilator element has a conical tip (FIG. 1, #14) and is retractable within the tubular channel (FIG. 2 and specification, page 3, lines 5-7). The tubular channel has an extremely small wall thickness of a maximum of 0.06 mm

(specification, page 2, lines 21-21) and is formed of a hard plastic (specification, page 2, lines 16-17) such as polyamide or polyester.

The one independent claim, claim 1, is supported by at least the following reference to the specification, reference character and figures:

1. An introduction device (page 5, line 6; FIG. 1, #10) for introducing an object into a vessel of a body, comprising:

a tubular channel (page 5, line 17; FIG. 1, #15) and a dilator (page 5, line 7, FIG. 1, #11) carrying the channel, wherein the dilator comprises a conical tip portion (page 5, line 12; FIG. 1 #14) and is adapted to be retracted (page 3, lines 5-7) from the channel, wherein the channel has a wall thickness not larger than 0.06 mm (page 5, line 19) and is formed exclusively of a hard plastic material (page 2, lines 16-17).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

This appeal has one issue, namely whether the pending claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Fischell et al. (EP 0 596 172 A2) in view of applicant's own application, Siess et al (US 2004/0044266). More particularly, the issue boils down to whether the primary reference describes or even suggests an introducer that includes an extremely thin sheath or channel formed **exclusively** of plastic in combination with a retractable dilator. The applicants maintain that the Examiner mischaracterizes the structure and interrelationship of the various components of the cited reference in a strained and unreasonable effort to find the present invention therein.

VII. ARGUMENT

The rejected claims all require the introducer device to include a retractable dilator in combination with a channel that is in effect readily deformable. The channel is claimed in terms of a **structure** that is readily deformable, i.e. it is claimed in terms of its composition and thickness - "formed exclusively of hard plastic" with a wall thickness of "not larger than 0.06 mm." Such limitations were selected as they necessarily render an introducer sheath having such properties to be readily deformable and effectively serve to distinguish the prior art. Moreover,

it avoids any confusion that could otherwise arise in attempting to quantify the "readily deformable" function of the present invention versus a "**non**-kinking" function of the prior art including that of the cited reference.

VII. THE SHEATH OF THE PRIMARY REFERENCE IS NOT FORMED EXCLUSIVELY OF PLASTIC

In the case of the primary reference, the sheath that is described therein is a **metal** reinforced structure which is therefore clearly not formed "exclusively of plastic." More particularly, the introducer sheath (10) of the cited reference is described in the abstract of the document (Exhibit 2) as having an internal **metallic** helical coil (12) within a thin plastic covering (20). As such, the device embraces the conventional approach wherein the sheath is configured so as to **resist** deformation rather than allow deformation to readily occur, as is articulated in the reference at page 2, line 17 and even more unequivocally at page 2, line 58: "This ratio of wire width to wire thickness is a very important consideration in the design of the sheath **in order to prevent the sheath from collapsing**." Not only does a reinforcement structure increase the overall diameter of the device but would additionally require the insertion of a dilator ("not shown" page 4, line 53) in the event the introducer does in fact become deformed.

In contrast thereto, the present invention represents a thoroughly unconventional approach in this regard as it had unexpectedly been found that the substantial axial force that was typically needed to correct any deformation of a deformation-resistant sheath was the result of the sheath's own resistance to deformation rather than the forces applied by the surrounding tissue. Accordingly, because the channel element of the present invention is readily deformable, it does not require the reinsertion of a dilator in order to apply sufficient axial force to correct any deformation as the axial force generated by the insertion of an intravascular device is sufficient.

IX. THE REINFORCEMENT COIL OF THE PRIMARY REFERENCE IS NOT A DILATOR AND IS NOT RETRACTABLE

In an effort to find the claimed structure in the sheath shown and described in the primary reference, the Examiner undertakes a hypothetical disassembly of the sheath and then refers to only its outer covering as the 'sheath' while characterizing its inner reinforcement coil as a retractable 'dilator'. This is a wholly unreasonable characterization of the structural elements as well as an unreasonable interpretation of the teachings of the reference. Both the reinforcement coil as well as its plastic covering are part and parcel of the sheath. Not only is the outer plastic covering said to be effectively fused to the underlying metal coil (such as by heat shrinking, hot dipping or over extrusion – page 3, lines 27-32) but its projections into the spaces between adjacent windings of the coil (Figs. 2A-3D) serve to mechanically lock the covering to the coil. Retraction of the reinforcement coil relative to its plastic covering is therefore effectively and positively precluded. Additionally, the proximal end of both the outer covering as well as the reinforcement coil are described as being "moulded" to the adaptor 30 that is situated at the proximal end of the device (page 4, lines 53-73). Clearly, such construction defies disassembly while the reference clearly teaches away from any notion of the reinforcement coil being retractable from its covering. It should also be noted that the sheath (covering plus reinforcement coil) described in the reference is for use in conjunction with a dilator (page 4, line 53) that is not shown. Characterizing the covering of a reinforced introducer sheath as the introducer sheath is no more reasonable than characterizing its reinforcement coil as a dilator when the coil reinforced sheath is to be used in conjunction with a dilator.

In straining to find the claimed structure in the cited reference, the Examiner also completely ignores the teachings of the reference which clearly teach directly away from the concept of an introducer sheath that is readily deformable. Not only is the device referred to in its very title as "non-kinking", but the reliance on the reinforcement coil to prevent the collapse of the sheath is specifically mentioned throughout the specification. The metal reinforcement coil is therefore very much a integral component of the sheath and as such teaches away from a deformable channel, let alone one that is formed exclusively of a thin plastic.

While the secondary reference (Exhibit 3) is relied upon by the Examiner for its disclosure of a dilator with a conical tip, the reference similarly relies on a conventional rigid tubing (page 2, paragraph 35, line 3) as the conduit through which an intravascular is introduced and as such suffers from the same shortcomings that are inherent in the sheath of the primary reference. Moreover, it comprises the type of device that is described in the second paragraph of the present application and is precisely the type of device the claimed invention improves upon.

In sum, neither reference recognizes that a readily deformable channel in combination with a retractable dilator can provide the benefit of minimizing the overall cross section while nonetheless facilitating the insertion of an intravascular device therethrough. The cited references neither suggest such an approach nor describe a structure that can reasonably be interpreted as having the claimed elements.

X. CLAIMS APPENDIX

See Exhibit 1.

XI. EVIDENCE APPENDIX

None.

XII. RELATED PROCEEDINGS APPENDIX

None.

XIII. CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not obvious over the cited references and that the Examiner's rejection of claims 1-8 was therefore erroneous. Appellant respectfully requests reversal of the rejection of claims 1-8.

Respectfully submitted,

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LIST OF EXHIBITS

EXHIBIT	DESCRIPTION
1	Appealed Claims
2	Fischell et al. (EP 0 596 172 A2)
3	Siess et al. (US 2004/0044266 A1)